An Overview of NHRC Medical Engineering Process

Ruth A. Bush
Janet L. Dickeson
William E. Hamilton

Naval Health Research Center

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Naval Health Research Center
P.O. BOX 85122
San Diego, California 92186-5122

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Naval Health Research Center
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Abstract

The rapidly evolving technological environment presents a wealth of opportunities to the warfighter**.** There is a strong need to be able to systematically identify, develop, and integrate emerging medical technologies into mature, functional, and cost-effective systems that are capable of supporting medical readiness and meeting operational capability requirements. The NHRC Medical Engineering Process provides a comprehensive process of checks and balances throughout the Research, Development, Test and Evaluation cycle for field medical technologies. The goals of this program include facilitating the transition of research and development (R&D) efforts to Department of Defense programs of record, decreasing time to implementation, reducing risk of application failure, increasing return on investment of R&D dollars, and providing the warfighter with state-of-the-art, reliable tools that increase survivability. To ensure the technologies produced meet immediate and long-term requirement capabilities, NHRC is maintaining collaborative relationships with customers such as the Navy Medical Chief Information Officer, the Naval Warfare Development Command, the Marine Corps Warfighting Lab, and the Theater Medical Information Program Joint Program Office. This document details the design, development, and initial implementation of the process during the period 1 October 2002 through 1 July 2005.

Background

Because technological capabilities, personnel resources, mission needs, and security concerns vary with the nature of the deployment setting, naval forces must be provided with medical devices and information systems that fit a wide variety of operating conditions. Furthermore, the steady development of cutting-edge medical technologies requires the ability to systematically identify, develop, and integrate applicable concepts into mature prototype systems that functionally and cost-effectively support medical readiness and meet operational capability requirements.

The Chief of Naval Operations has published his vision for Navy's transformation, Sea Power 21, to meet the challenges of the twenty-first century. The key concepts in Sea Power 21 of Sea Basing, Sea Strike, and Sea Shield will allow the Navy to meet these challenges. (Clark, 2002). Furthermore, the new Joint Capabilities Integration and Development System (JCIDS) is a top-down process designed to improve coordination with government departments or national agencies resulting in capabilities documents tailored to each phase of the acquisition process. The system includes an identification process to determine capabilities gaps, to set priorities, and to develop joint solutions to fill the capabilities gaps. (Chairman of the Joint Chiefs of Staff Instruction, 2005) These developments have highlighted the need to transform Expeditionary Health Service Support (EHSS) capabilities to align with goals of Sea Power 21 and are the driving force behind the Navy transforming its historical method of generating requirements into a unified and streamlined process.

In response, the Naval Warfare Development Command (NWDC) has been tasked to stand up a Navy Force Health Protection 21 Combat Development Process (NFHP-21 CDP). This process will identify and assess EHSS operational requirements and capabilities. The new process, under development at NWDC, is designed to align with and to support the JCIDS program. As such, the NFHP-21 CDP includes four complementary phases to the JCIDS analytical approach. During the Force Capability Development phase, capability gaps are identified and a Universal Needs Statement (UNS) is developed. When the completed UNS is entered into the NFHP-21 Combat Tracking System, the Requirement Development phase begins. As part of this phase, the UNS is reviewed and sent to the Doctrine, Organization, Training, Materiel, Leadership, Personnel and Facilities (DOTMLPF) working group for analysis and for their recommendation of a materiel or nonmateriel solution. During the Prioritization and

Resourcing phase, the previously identified requirements are determined to be critical or not critical for the fleet/force mission. Finally, during the Capability Fielding and Transition phase, the acquisition process is initiated to field the new capability. Non-materiel solutions will be handled through the DOTMLPF process in a similar way, ending with Fielding and Transition.

Application

The Naval Health Research Center (NHRC) Naval Medical Engineering Process (NMEP), working in conjunction with the later three phases of NFHP-21 CDP, is intended to gather operational requirements, to assess candidate technological solutions for those requirements, and to design and to develop technological solutions as appropriate. The process includes the test and evaluation (T&E) of both prototypes and commercial-off-the-shelf technology intended to support deployed medical caregivers as they provide combat casualty care and conduct medical surveillance. The NMEP provides a comprehensive checks and balances process throughout the RDT&E cycle for field medical technologies.

There are four phases in the NMEP: Technology Watch (TW), Quality Assurance (QA), Verification and Validation (V&V), and Field Test and Evaluation (FT&E). During the TW phase requirements are validated and expectations are set for development. The QA phase incorporates steps to closely monitor development against those validated requirements. During the V&V phase, a series of rigorous tests are conducted to demonstrate that the product or system has been built according to specified functionality. Military Utility Assessments (MUAs) and Military Feasibility Assessments (MFAs) are conducted during the FT&E phase in operational and exercise settings to ensure that the new product or system meets desired operational capability requirements, and does so in a way that is practical and cost-effective from an operational mission perspective.

NMEP goals include the following:

1. Facilitate transitioning research and development (R&D) efforts to the Department of Defense (DoD) by providing high quality assurance.
2. Reduce time to implementation by validating confidence in applications before taking final steps to transition.
3. Reduce risk of application failure prior to deployment in operational settings.

4. Reduce exposure to financial loss due to application insufficiencies.
5. Increase return on investment of R&D dollars.
6. Increase efficiency and customer confidence in the R&D process.
7. Provide the warfighter with state-of-the-art, reliable tools that increase survivability.

To mitigate the potential gap between RDT&E funding and funding for continued sustainment through the Program Objective Memorandum and budget process, as soon as a candidate product or system is selected for QA, V&V, or FT&E, a technology transition plan (TTP) is initiated. A sample TTP can be found in the Appendix. The TTP is modeled after the Office of Naval Research (ONR) Future Naval Capability Technology Transition Agreement. Initiating a TTP assists the research community in identifying transition partners, understanding their needs and processes, and actively working to identify transition opportunities in terms of their schedules and budgetary constraints. An additional benefit of the TTP process is that products or systems with no viable transition partners identified prior to entering the FT&E phase can be targeted by leadership in the research community for discontinuation.

Another approach designed to ensure that a candidate project meets the required needs is the use of configuration management, a discipline that applies technical and administrative direction and surveillance over the life cycle of items to accomplish the following: (1) identify and document the functional and physical characteristics of configuration items; (2) control changes to configuration items and their related documentation; (3) record and report information needed to manage configuration items effectively, including the status of proposed changes and implementation status of approved changes; and (4) audit configuration items to verify conformance to specifications, drawings, interface control documents, and other contractual requirements.

Because products and systems are increasing in complexity, to the point that no individual has the ability to comprehend the whole or the technical depth to understand all of its parts, management of technological information is increasingly important. Technologies come and go at a rapid pace, increasing the number of solution options to be evaluated for any product or capability. Meanwhile, the immediacy of the need to field an operational capability has made it essential that the process times in each of the NMEP phases be minimized. Budgets are declining, highlighting the need for effective strategies that include reuse of technologies,

components, decisions, and tests. The ability to design the “right thing, right the first time” is paramount. This implies that the customer must be fully engaged at all stages of the NMEP. Finally, naval customers expect that developers follow a comprehensive product development process that yields 100% verification that their requirements have been implemented successfully. For the reasons listed above, the NMEP employs the Telelogic requirements management tool, Dynamic Object Oriented Requirements System (DOORS), throughout all process phases (Telelogic North America Inc., Irvine, CA).

DOORS allows effective management and control during product development. Changes inevitably occur as solutions are implemented, often with little or no analysis of the effect of those changes. DOORS provides the analysis tools to reveal which requirements will be affected by a change. Requirements documents are often uncontrolled with changes occurring throughout the entire life cycle. A Change Proposal System within DOORS controls those changes and relates any changes back to cost and schedule so that a clear view of product status is provided.

Technology Watch (TW)

The TW phase of the NMEP is designed to review the plethora of new technologies produced by the government and industry, and to identify and prioritize the most promising candidates against validated requirements, such as the NFHP-21 CSDP. Additionally, it is in this phase that a gap analysis is performed and future R&D needs identified. The objective of this part of the process has been to develop a concept of operations (CONOPS) for NHRC to work with NWDC to support an approach for developing, tracking, and approving medical requirements as well as to provide research support for evaluation and/or validation of any prospective technological solutions. It is important to note that NHRC and the NMEP do not validate or own the requirements. Such requirements belong to programs like the Naval Air Systems Command, Naval Sea Systems Command, and the TMIP, which in turn meet the requirements of JCIDS. Developing the CONOPS includes design of an automated system to track processing of prospective medical requirements coming to NWDC and conducting a technology survey using search engines such as Google and research to evaluate “best-fit” technologies for new medical requirements, such as shipboard surgical systems or field medical surveillance.

Quality Assurance(QA)

The focus of this work will address system scalability, reliability, and security elements of prototype information technology (IT) solutions. Quality assurance efforts ensure that hardware and software meet standards for security, data handling (i.e., Health Insurance Portability and Accountability Act [HIPAA]), and communications (e.g., IT-21, the Navy Information Technology for the 21st Century program). While both military and industrial standards exist to verify such security, the scope of such efforts varies according to the range of operational application. Continental United States versus in-theater employment, or joint service system integration, for example, can expand the extent of security analysis tasks.

There are two main objectives to this stage. The first objective is to provide quality assurance support for the NHRC R&D Information Management/Information Technology Process. This iterative process involves testing medical software applications that are currently under development. Black box testing and white box testing are used in this phase. Black box testing purposefully takes place without any knowledge of the internal design of the code and relies on behavioral tests developed from functional and compliance requirements. The test engineer proceeds through test cases (scripts) that contain detailed steps for testing each requirement. A comparison is documented between the expected test results and the observed actual results.

During white box testing, the internal logic of an application's code is considered. Tests include the analysis of source code, conformity to requirements, and high-level design. Test cases are designed with detailed steps that test each path in the code, as well as describe the corresponding expected results. A comparison is documented between the expected test results and the observed actual results. Documenting the results of the NHRC R&D IM/IT Process, and communicating this information in DoD format meets the objective of supporting more-effective medical decision making and may lead to improved procedures for treating combat casualties.

Verification and Validation (V&V)

The V&V process includes verification and validation studies on applications submitted via third parties. Steps in this phase include gleaning functional requirements from the application documentation and available materials, including compliance documentation; gap analysis to determine missing functional requirements and identify unnecessary functional

requirements; preparing test cases detailing steps for testing each functional requirement; executing the test scripts; and recording test results. A Report of Findings is generated in this phase detailing the conclusions of the V&V team, stating the methodology used to arrive at these conclusions, and providing the results of each test case in summarized format. This report is the basis upon which the product or system is deemed acceptable for further consideration by naval medical decision makers. During this part of the process, medical technologies undergo systematic, evidence-based validation to corroborate (or disprove) the performance claims of their developers and to prepare them for field testing. The verification takes place within an established framework that incorporates industry standards and DoD practices.

Four deliverables are produced for each product or system tested: Installation and Initial Assessment, Requirements Specification, V&V Plan, and a Report of Findings. The Report of Findings includes one of four possible recommendations: integrate the application into a suite for field testing, approve the application for general use, reject the application for defects in workmanship or quality, or accredit the application for transition. In an effort to keep the work independent and objective, V&V team members cannot participate in technological development.

Field Test and Evaluation (FT&E)

The function of the FT&E phase is to answer the question: “Was the correct thing built?” This is the part of the process that determines the *utility* of an application to the Navy and Marine Corps, which must be done by active military personnel in the field or in an environment that replicates the field anticipated operational setting in which the technology will be employed.

The FT&E team recommends venues; identifies requirements for approved venues; implements upgrades at long-term venues; communicates the requirements and schedules to all third parties; coordinates participation at the approved venues; surveys MILPERS who participate at the venues for feedback on the viability, usability, and utility of the applications; collects and coordinates all After Action Reports tracking to resolution; executes exit strategies (i.e., collecting all hardware and software previously deployed, circulating surveys); and produces an MUA and MFA with regard to the utility of applications tested in the field.

Lessons learned in the QA, V&V, and FT&E phases are fed back to the Requirements/Technology Watch phase as potential new requirements, enhancement requests

and Technical Assistance Requests. The identified user feedback is provided to the product-line developers, thus ensuring the systems developed meet the users' requirements. FT&E is the NMEP phase that provides the interface between the integrated medical technology production line and the user base by coordinating limited planned deployment of the integrated systems and T&E of such systems.

Progress through 1 July 2005

Examples of products that have gone through one or more of the NMEP phases:

1. Field Medical Companion (FMC): Delivers immediate, critical information to first responders and warfighters in far-forward and remote environments.
    a. May through September 2004 – FT&E of the consolidated FMC containing both Medical Information Modules and Patient Data Capture on one handheld device.

2. Medical Data Surveillance System (MDSS): Designed and developed as a Web-enabled system for the medical surveillance of Navy and Marine Corps deployed forces. The primary objective of the system was to rapidly detect medical threats through the analysis of routinely collected patient data.
    a. 2003 – T&E of MDSS at Navy and Marine Corps medical treatment facilities. (Melcer, Bohannan, Burr, Leap, Reed, & Jeschonek, 2003).

3. Shipboard Medical Administrative Readiness Tool (SMART): This prototype Web-based application was designed to provide tactical and medical command and control assessments of the medical readiness of the force.
    a. March 2004 – Completed testing on SMART prototype
    b. March 2004 – Issued draft final report on SMART, including an analysis of subject matter expert opinion and functionality information.

4. Telemedicine: This effort evaluated the use of telecommunications technologies to assist in delivering health care to remote or distant treatment sites, such as aboard ship.
    a. 2004 – Assessment of interoperability (Reed, Burr, & Melcer, 2004)
    b. 2003 – Evaluation of telemedicine satisfaction among Navy radiologists (Bohannan, Strychacz, and Melcer, 2003)
    c. 2002 – Current research in and future directions of Navy telemedicine (Reed, Burr, & Melcer, 2002)
    d. 2002 – Retrospective evaluation of the development of a telemedicine network in a military setting (Melcer, Crann, Hunsaker, Deniston, & Caola, 2002).
    e. 2002 – Prospective evaluation of ENT telemedicine in remote military populations seeking specialty care (Melcer, Hunsaker, Crann, Caola, & Deniston, 2002)

5. Tactical Medical Logistics Planning Tool (TML+): TML+ includes a simulation tool that models the patient flow from the point of injury through more-definitive care, and a research tool that supports systems analysis, operational risk assessment, and field medical services planning.
    a. May 2004 – Initial TML+ testing
    b. May 2004 – Review of available materials for TML+ and plan for user training and new surveys for evaluation of the software complete.
    c. April 2004 – Review of current version of the TML+ User's Manual, and the Methodology Manual.

6. Tactical Medical Coordination System (TacMedCS): Non-physical-contact data transmission and storage media are used to uplink casualty information to a theater information network, providing enhanced situational awareness and increased casualty accountability
    a. April through July 2004 – Participated with the Marine Corps Warfighting Lab (MCWL) in the test and evaluation of TacMedCS.

7. Humanitarian Aid Projects:
    a. September 2004 – Integration and T&E of a suite of tools to take to Terminal Fury 2004 in November 2004
    b. June 2004 – Integration and T&E of a suite of tools to take to Vanguard 2004
    c. March 2004 through May 2004 – Support data collection and evaluation for Cobra Gold ’04 exercise

Benefits

NHRC has applied the rigor of this engineering process, which incorporates QA in support of technology research and development rather than generating new products, to the product pipeline and increased the quality of its R&D and the products it transitions. NHRC is establishing relationships with customers and transition partners such as the Navy Medical Chief Information Officer, NWDC, MCWL, and the TMIP-J Program Office to ensure that the products and systems produced meet the immediate and long-term requirement capabilities.

The NMEP will guarantee that devices work within austere conditions and are interoperable with existing devices. In the future, the process will expand to continue to reduce Science and Technology (S&T) risk through minimizing duplicative effort, maximizing cost avoidance, and testing capabilities within an expeditionary environment. This process will provide acquisition agencies with the data needed to make informed acquisition or development decisions and to select from multiple systems considered for Navy or Marine Corps use.

In its initial instantiation, the NMEP process has reduced cost per project, improved quality across all projects, and increased customer confidence in the R&D projects contemplated for transition to the appropriate program of record. The NMEP has supported NWDC’s response to JCIDS requirements and provided the flexibility to adapt as requirements are updated and modified.

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Appendix

Naval Health Research Center

TEMPLATE FOR MEMORANDUM OF AGREEMENT (MOA)

Memorandum of Agreement Between Naval Health Research Center and [Target Acquisition Program] for the S&T Transition of [Title of transitioning technology]

1. This Memorandum of Agreement (MOA) between the Naval Health Research Center (NHRC) and [Target Acquisition Program] program defines the path of transition for [number] of R&D products; (1) [technology 1], and (2) [technology 2], etc. – can be expanded to list as many technologies as needed]. NHRC performs a [multi-]year technology development program that will result in these tools and strategies that the [Target Acquisition Program] program will incorporate upon successful demonstration. [Depending on project, may need to include brief description of major program objectives, current phase of acquisition life cycle, and project initial operational capability date.]

[Information in the next four sections to be provided by the Program Office]

2. [Name of Target Acquisition Program] Program Manager: Name (Command, code, etc.)

Program Manager/Project Officer. Program manager and individual in program office responsible for day-to-day management with contact information.

3. Acquisition Program Technology Need:

Brief description of the benefit that this technology will bring to the acquisition program, or need satisfied. Where possible, relate benefit to the Operational Requirements Document (which is being phased out and replaced by a similar document called the Capabilities Development Document [CDD]) and Key Performance Parameters (KPP). Desired user capabilities, expressed in terms of KPPs and other parameters, should be defined in terms of the following:

- Quantifiable metrics (e.g., speed, lethality) of performance to meet mission requirements affordably; and
- The full range of operational requirements (reliability, effectiveness, logistics footprint, supportability criteria, etc.) to sustain the mission over the long term.

In their initial stages, the KPPs are general, broadly defined and become more specifically defined as a program matures. Include needed dates for specific capabilities. The Program Office should provide an opinion of technology maturity at transition. This may be done by risk level or by using the following Technology Readiness Level (TRL) nomenclature. TRLs are a measure of

technical maturity. They do not discuss the probability of occurrence (i.e., the likelihood of attaining required maturity) or the impact of not achieving technology maturity.

Technology Readiness Level	**Description**
1. Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.
2. Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.
3. Analytical and experimental critical function and/or characteristic proof of concept.	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.
4. Component and/or breadboard validation in laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.
5. Component and/or breadboard validation in relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high fidelity" laboratory integration of components.
6. System/subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in simulated operational environment.
7. System prototype demonstration in an operational environment.	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include

	testing the prototype in a test bed aircraft.
8. Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.
9. Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.

Definitions:
Breadboard: Integrated components that provide a representation of a system/subsystem and which can be used to determine concept feasibility and to develop technical data. Typically configured for laboratory use to demonstrate the technical principles of immediate interest. May resemble final system/subsystem in function only.
High Fidelity: Addresses form, fit, and function. High fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.
Low Fidelity: A representative of the component or system that has limited ability to provide anything but first order information about the end product. Low fidelity assessments are used to provide trend analysis.
Model: A reduced scale, functional form of a system, near or at operational specification. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
Operational Environment: Environment that addresses all of the operational requirements and specifications required of the final system, to include platform/packaging.
Prototype: The first early representation of the system that offers the expected functionality and performance expected of the final implementation. Prototypes will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
Relevant Environment: Testing environment that simulates the key aspects of the operational environment.
Simulated Operational Environment: Environment that can simulate all of the operational requirements and specifications required of the final system or a simulated environment that allows for testing of a virtual prototype to determine whether it meets the operational retirements and specifications of the final system.

4. Transition Plan. [Also called Integration Strategy]

Describe the process for integrating the technology into the acquisition program. Include elements of acquisition strategy – evolutionary acquisition, block upgrade, etc., as well as required contractor-to-contractor agreements. Include the Program Elements (PE's) that

acquisition intends to fund the transition and annual PE funding levels committed to the transition program. Also include the associated transition FY.

Transition: FY-00 Completion
[Target Acquisition Program]
R&D [Funding Information]
Funds Allocated to Transition ($M)

FY02	FY03	FY04	FY05	FY06	FY07	Total Program
						1.00

[Information in the next six sections to be provided by the S&T Activity]

5. Description of Technology/Capability:

Description of Technology or Capability to be Delivered. Brief description of what the S&T activity intends to develop for transition to the acquisition program. Include capability delivery dates.

[The ONR example included this funding table]
S&T Funding ($M)

PE	Project	FY02	FY03	FY04	FY05	FY06	FY07

6. NHRC Technology Manager: Name, [Project Name] Project Manager, NHRC

7. Current Status.

Status Summary. Summarize current state of development. Identify primary areas where additional development is required. Technology Readiness Levels are a measure of technical maturity and can be used to assess readiness to transition.

1. Provide estimate of current TRL (use previously included table of levels.)

2. **Risk Analysis**. Major areas of risk, prioritized, with planned mitigation activities include technical (e.g., producibility, affordability, sustainability) cost, and schedule risks.

8. Technology Development Strategy:

Outline approach planned. Efforts required beyond those currently underway, integration plans if multiple projects are planned. Planned ATD or ACTD developments, if applicable.

9. Key Measures of Transition Readiness

Product	Current	Interim	Final Objective

Identify the key parameters or attributes that will be used to measure whether or not the technology development effort is proceeding appropriately. Include parameter to be tracked, current state, interim progress estimates, and final objective.

10. Program Plan

Tasks	FY02	FY03	FY04	FY05	FY06	FY07

_____ _____

Program Manager, [Name of Project]
[Name of Acquisition Program] Technical Manager, NHRC

Useful Acronyms

ACTD: Advanced Concept Technology Demonstrations

ATD: Advanced Technology Demonstrations

CDD: Capabilities Development Document

FY: Fiscal Year

KPP: Key Performance Parameters

MOA: Memorandum of Agreement

NHRC: Naval Health Research Center

ORD: Operational Requirements Document

PE(s): Program Element(s)

R&D: Research and Development

RDT&E: Research, Development, Test and Evaluation

TMIP-J: Theater Medical Information Program - Joint

TRL: Technology Readiness Level

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6. AUTHORS
Ruth A. Bush, Janet L. Dickieson, William E. Hamilton

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Naval Health Research Center
P.O. Box 85122
San Diego, CA 92186-5122

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Commander, Navy Medical Support Command
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